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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of	:	
George McBride, et al	:	
Filed: 03/27/2000	:	EXAMINER: PAUL L. KIM
Title: Medical Testing Internet Server System and Method	:	Art Unit 2857
Serial No.: 09/535,185	:	

DECLARATION UNDER 37 C.F.R. 1.131
By
ROBERT ROYCE

I, ROBERT ROYCE hereby declare as follows:

1. My address is 2427 Huber, Mesa, AZ 85213

2. At least as early as July 9, 1999, George McBride and I conceived the invention that is the subject of the above-identified patent application. Evidence of this conception is an emailed executive summary of the project dated July 09, 1999, a redacted copy of which is attached as Exhibit 1.

3. Subsequent to the conception of the invention George McBride and I were diligent in reducing the invention to practice as evidenced by a continuous development activity pertaining to the reduction to practice of the invention up to and beyond the filing date of the above-identified patent application. At no time from the date of conception of the invention through the filing date of the above-identified application did the development activity cease.

4. Subsequent to July 9, 1999, a new corporate entity was formed, Cardiobeat.com, develop and market the invention. I reviewed and provided input to George Mc Bride in the preparation of a development plan for the invention, one version of which was sent by email to me by George McBride and which is attached hereto as Exhibit 2.

5. Subsequent to at least as early as July 9, 1999 I contacted engineering firms to contract with them to assist in reducing the invention to practice. As a result of this activity, proposed design approaches to implementing aspect of the invention was received by me from Warren Williamson in an email dated August 17, 1999. A copy of the email as forwarded to George McBride is attached as Exhibit 3.

6. Subsequent to at least as early as August 17, 2002 I worked substantially continuously and full time in reducing the concept to practice as an employee/owner of Cardiobeat.com

7. At frequent times throughout the development activity of the invention, George McBride and I consulted with Dr. James Buell, regarding medical applications and impedance cardiography which is used in the illustrative embodiment of the invention. One email communication that I received from Dr. Buell is attached hereto as Exhibit 4 dated 9/18/1999.

8. At all times subsequent to the conception of the invention, both George McBride and I continued to work on the reduction to practice of the invention including development of software. As part of my full time activities in reducing the concept to practice, I prepared a status report that I sent to George McBride by email dated October 15, 1999, attached as Exhibit 5, that discusses the development of aspects of the invention and includes an attached flow chart. The flow chart indicates that a portion of the database activity that is part of the reduction to practice of the invention is "about ½ done at this time".

9. On December 22, 1999, a meeting was held to review the development status of the invention. A copy of the overview of that development status is attached as Exhibit 6. I participated in that meeting and reported on activities indicated in the attached overview.

10. From December 23, 1999 through March 27, 2000, I along with George McBride had several meetings with patent attorney Donald J. Lenkszus to disclose our invention and the illustrative embodiment development with him so that he could prepare and file patent applications on the subject invention and related inventions.

11. Warren Williamson of W.L. Williamson & Associates provided engineering services throughout this stage of the development activities. Mr. Williamson provided a quotation for engineering service in a letter to me dated January 7, 2000, attached as Exhibit 7, as a result of earlier conversations that I had with him relative to providing engineering services relative to implementation of the invention at the direction of myself and George McBride. The quotation was accepted and Mr. Williamson provided engineering services for this aspect of the project beginning in January 2000.

11. Mr. Williamson provided engineering services as indicated by a report on Timing of Test Waveforms dated 2/1/00 attached as Exhibit 8; a communication, attached as Exhibit 9, regarding communications protocol dated 2/21/00 as revision 1 to an original dated 2/9/00; a document titled "Cardiobeat data contents" dated 2/28/2000, attached as Exhibit 10; and an invoice for services dated March 6, 2000, attached as Exhibit 11.

12. All the attached documents are true copies of original documents.

13. Throughout the period from conception of the invention through the filing date of the above-identified patent application, George McBride and I continuously and diligently worked on reducing the invention to practice either through our direct personal efforts and/or through direction of others in implementing various aspects of the product embodying the invention. I worked substantially full-time on reducing the invention to practice from at least as early as August 17, 1999 through the date on which the above-identified patent application was filed.

INVENTOR: McBride et al attorney docket: CARDIOBEAT-2
TITLE: : Medical Testing Internet Server System and Method

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Robert Royce

Date: OCTOBER 20, 2003

EXHIBIT 1

GMcBride/cardiobeat.com

From: George McBride
Sent: Friday, July 09, 1999 13:27
To: 'bob@softque.com'
Subject: FW: Executive Summary - Cardiac Technology Business Plan

Bob,

The following Executive Summary was sent to Mike Buchanan for his comments. Larry and I would like your reaction and comments as a "fresh" reader. When you work on a document extensively the substance becomes familiar and objectivity is lost. Any comments to improve clarity would be appreciated.

The purpose of the summary is to sell the idea and convey the scope. Details (how this will happen) will be integrated into the business plan. We expect that you will be frustrated by the broad sweep of the summary. Even with that, will it sell the concept?

George McBride
Asset Technologies, Inc.
Direct Phone: 602-418-0464
Office: 480-998-8900
Fax: 480-922-0500
Email: gmcbride@assettech.com
Web Page: www.assettech.com

-----Original Message-----
From: George McBride
Sent: July 09, 1999 13:18
To: J. Michael Buchanan (E-mail)
Cc: Larry Macdonald (E-mail)
Subj ct: Executive Summary - Cardiac Technology Business Plan

Mike,

Please comment on this executive summary. Does it tell the story?
Lets talk about how to proceed and how quickly we can move. The funding requirement is based on having a product available in 6 months with full deployment in a year.

Thanks again for the hospitality.

Draft Executive Summary.

CONFIDENTIAL, DO NOT COPY...

DiagnosticDoctor.com

Executive Summary

About Cardiac Technology

Cardiac Technology (CT) has developed and is selling non-invasive diagnostic systems. The first product is Hemodynamic Monitoring (HD) a procedure that replaces invasive heart catheterization providing information on stroke volume, cardiac output, systemic resistance, and cardiac function indices.
The Portable Cardiac Lab (PCL), the current product, is sold to hospitals, private physicians, and emergency technicians to obtain patient cardiovascular information utilizing a noninvasive procedure at very low cost.
The proprietary software that performs HD is the most advanced analytical software of its kind.

Mark t Opportunity

58 million Americans afflicted with heart disease spend $259 billion each year on treatment. The international mark t is over twice the size of the US. Ever increasing medical care costs demand cost effective treatment programs like HD. The incidence of heart disease increases as life expectancy increases, such as, congestive heart failure and strokes. Hemodynamic parameters are critical in assessing cardiac function. Yet these parameters are currently difficulty and expensive to obtain. Curr ntly the preferred method of obtaining this information is invasive catheterization, which is exp nsive and life threatening.
HD can be sold to the consumer through an Internet implementation at a greatly reduced cost. The testing logic will be downloaded for each test. The data collection sensors can be connected into any PC with a serial port (or USB). HD software will be downloaded for each test on a fee basis. Test results will be stored in a database for use by physicians and others. The cost of the sensors can be reduced to less than [redacted] for the consumer market. Pricing a single HD procedure at [redacted] versus [redacted] for a catheterization will expand the market to anyone in need.
HD will establish a channel for distribution of other tests and procedures, such as, stress and blood pressure tests.
The FDA has approved HD for Cardio Dynamics, a competitor, along with Medicare reimbursement qualification. CT has not submitted an application for approval. Based on the Cardio Dynamics approval, CT expects that approval, when requested, will be forthcoming.

Testing over the Internet

As the cost of health care rises individuals are taking a greater role in their medical care for both preventive and remedial medicine. HD offers direct access to a key cardiovascular test for a small cost. Home testing is testing on demand for those with heart disease that require regular monitoring. Immediate access to key tests and equally rapid transfer of the results to the care group will become an essential part of quality treatment in the future.
Establishing this channel will provide for distributing other medical and health products. HD will be the first of many procedures sold over the Internet. Establishing this test will position the Cardiac Technology as a primary channel for medical care through the Internet.

Time to market

Rapid deployment is critical to dominating the market. The HD technology is state of art, tested, and complete. The Internet deployment capability must be completed for general deployment. CT plans to begin field-testing several hundred users in three months with larger tests in six months. Broad deployment would begin in 12 months.

Pricing and Revenue

The average cost per test is [redacted] If each of the 60 million Americans afflicted with heart disease used HD once each year, the rev nues would be [redacted] CT expects HD will be used address a broad range of cardiac concerns from health interest to intensive care.
The channel developed for distributing HD can be used for advertising and distribution of related products and services.

Funding & Financial Summary

Need for Funding

CT is seeking [redacted] in funding to deliver the PCL Test through the Internet.
Funding is required to

- develop the Internet delivery system,
- upgrade the diagnostic code,
- construct the administrative and customer management systems,
- build the database to hold the test data, and
- reduce the cost of the sensors.

Pro Forma Financials

Cost have been forecast for the first year only

Revenue and Costs are outlined in section ?? of the Business Plan

	Year 1	Year 2	Year 3	Year 4	Year 5
Average Revenue per Test	[redacted]				
Number of Tests	101,000	2,000,000	10,000,000	20,000,000	30,000,000
Revenue	[redacted]				
Costs					
Headcount	[redacted]				
Startup	[redacted]				
Manufacturing	[redacted]				
Total Costs	[redacted]				
Net Profit Margin	[redacted]				
Net Profit	[redacted]				

George McBride

EXHIBIT 2

GMcBrid /cardiobeat.com

From: George McBride
Sent: Sunday, August 15, 1999 22:30
To: Bob Royce (E-mail); Larry Macdonald (E-mail)
Subject: Two Pricings...

Gentleman,

The project plan has been adjusted to include additional resource for the Application development. The project plan should be frozen for plan generation.

A second plan was created that attempts to reduce costs to a plan containing [redacted] of cost. The Infrastructure expens s were also adjusted.

While the primary plan will be the [redacted] funding. If the price is too rich in share of the company, a [redacted] back up may be worth discussing.

Larry,

The concentration should be on the [redacted] plan.

But, if there is time, the reduced deferred Project Plan "Low Cost – 1-3..." and a new column in the Infrastructure tab of the spread sheet can be used to generate a plan that comes in around [redacted]. This would be a nice back up to the discussion if the question is asked, "Can you do it for less?". I have a meeting out of the office first thing, 0800 and will be in by 0900.

The spreadsheet and 2 project plans are attached.

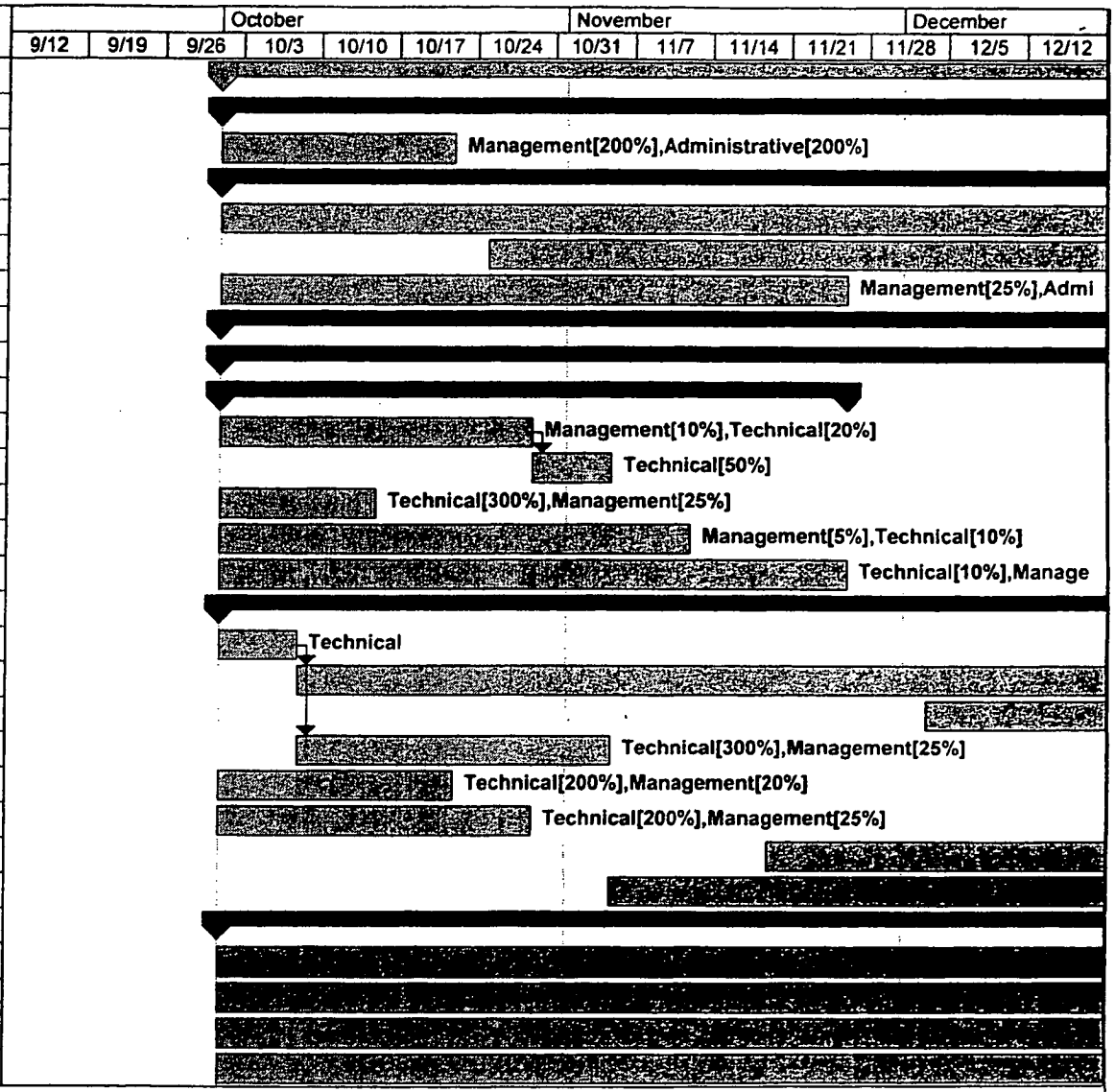

Low Cost - 1-3 Months Project ...


1-3 Months Project Plan.mpp (1...


First Cut Pro Forma.xls (116 K...

George McBride
Asset Technologies, Inc.
Direct Phone: 602-418-0464
Office: 480-998-8900
Fax: 480-922-0500
Email: gmcbride@assettech.com
Web Page: www.assettech.com

ID		Task Name
0		**Cardiobeat.com Milestones Project Plan Deployment**
1		**Valuation / Milestone Project Plan - Phase 1**
2		Start Up - Hiring, space, general Organization
3		**Administration**
4		Accounting System
5		Benefits Plan
6		Start recruiting
7		**Deploy Prototype System (25 Patients) (Start+ 3 Months)**
8		**Internet Deployment**
9		**Plant and Equipment**
10		Acquire appropriate hardware and software
11		Implement First Generation Web Servers
12		Create cardiobeat.com Web Page
13		Evaluate and select ISP's
14		Plan for general deployment volumes
15		**The Heart Test Functions**
16		Create Heart Test dB
17		Build Heart Test Download
18		Build Client Data Retrieval
19		Code Test Data Comm tools for user and back
20		Build doctor's office / clinic test procedure
21		Trendline evaluation and Reporting
22		Create Instructional Video Management Facility
23		Perform Heart tests employing Downloaded Ap
24		**Client Administrative Systems**
25		Create Administration dB
26		Build (Admin) Patient set-up
27		Customer Database Maintenance
28		Create client UI

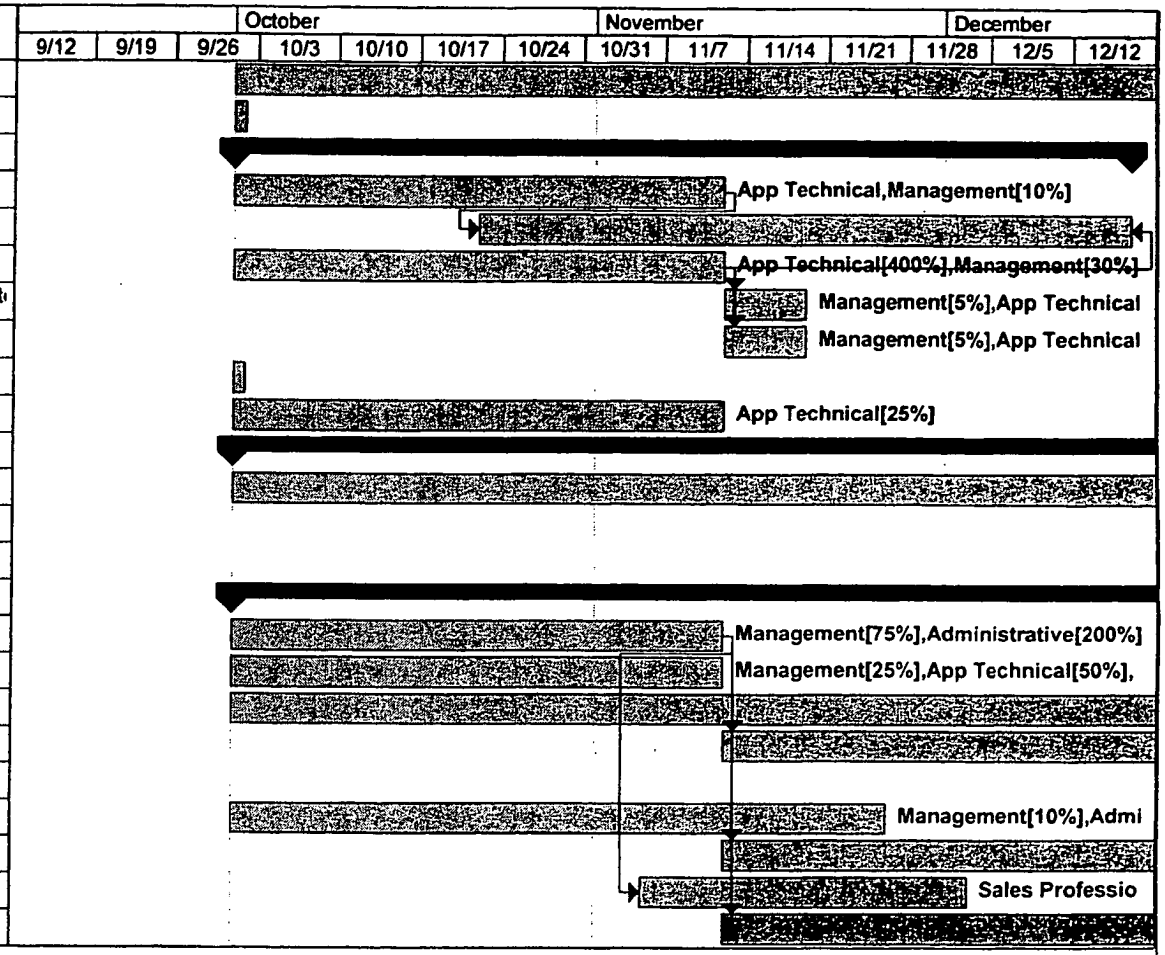


oject: Cardiobeat.com Milestones Project Plan Deploymer
ate: Wed 8/14/02

Task		Rolled Up Task		Project Summary	
Split		Rolled Up Split		External Milestone	
Progress		Rolled Up Milestone		Deadline	
Milestone		Rolled Up Progress			
Summary		External Tasks			

Note: Plan Created 8/15/1999

ID	Task Name
29	Install credit card charge facility
30	Create reporting
31	**Application**
32	Design General Distribution Test Interface
33	Build User Interface for test
34	Productize Heart Test Code (v1)
35	Split Code into patient and server applications for initial t
36	Test algorithms for point placement module
37	Code Filters
38	Code User Feedback
39	**Manufacturing**
40	Design first generation sensors
41	Select manufacturer and start volume tests
42	Manufacture First Generation Sensors (50 copies)
43	**Sales and Marketing**
44	Create sales and marketing Plan
45	Submit Patents
46	FDA Approval
47	Create plan for publicity / demand creation
48	Organize test subjects
49	Introduce concept to selected MD's
50	Create Instructional Video
51	Investigate Cardiologist Review of Test Data
52	Alliances / product sharing



oject: Cardiobeat.com Milestones Project Plan Deploymer
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Task		Rolled Up Task		Project Summary	
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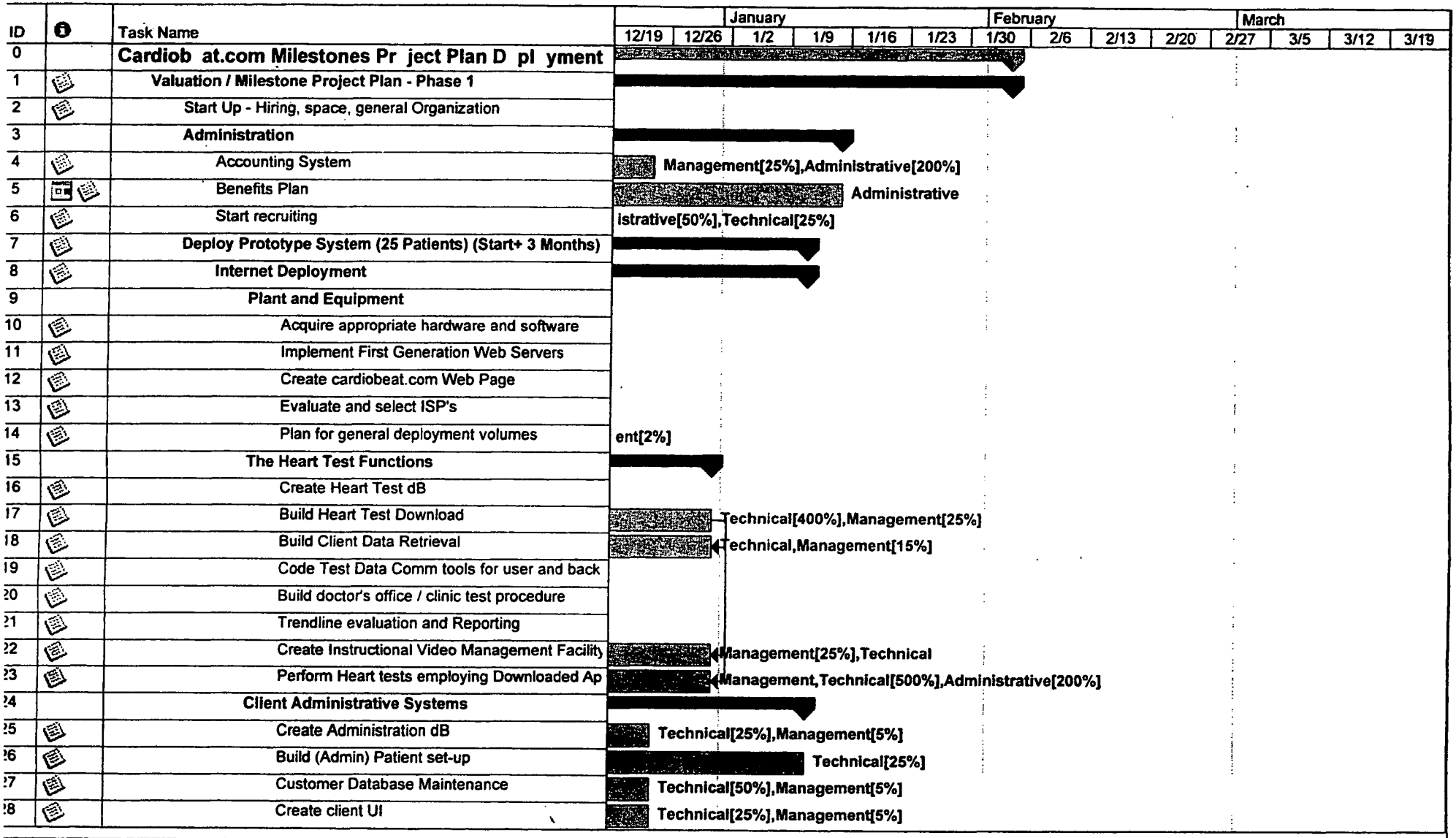
Progress		Rolled Up Milestone		Deadline	
Milestone		Rolled Up Progress			
Summary		External Tasks			

M Note: Plan Created 8/15/1999



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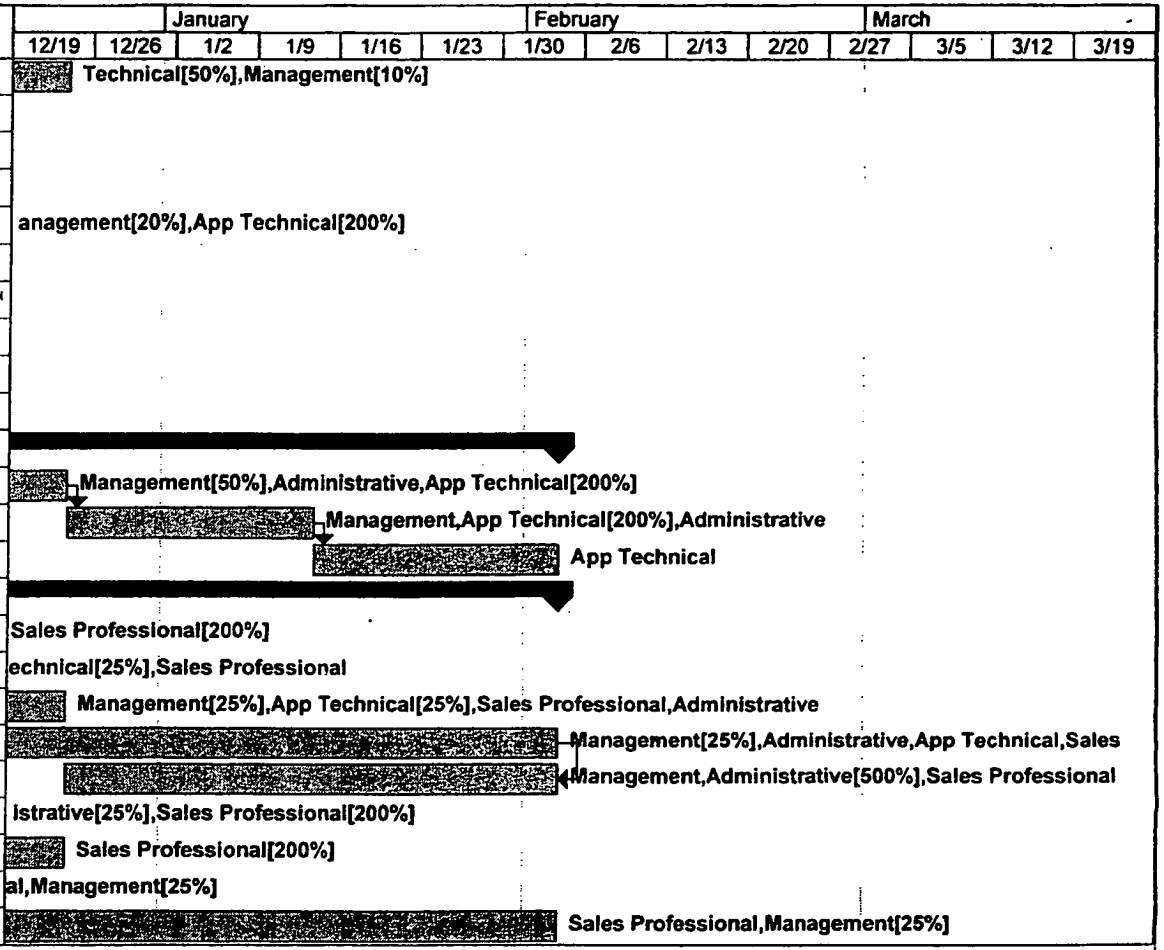
ıte: Wed 8/14/02

Task		Rolled Up Task		Project Summary	
Split		Rolled Up Split		External Milestone	
Progress		Rolled Up Milestone		Deadline	
Milestone		Rolled Up Progress			
Summary		External Tasks			

Note: Plan Created 8/15/1999

ID	Task Name	Resource Names
29	Install credit card charge facility	Technical[50%],Management[10%]
30	Create reporting	
31	**Application**	
32	Design General Distribution Test Interface	
33	Build User Interface for test	anagement[20%],App Technical[200%]
34	Productize Heart Test Code (v1)	
35	Split Code into patient and server applications for initial t	
36	Test algorithms for point placement module	
37	Code Filters	
38	Code User Feedback	
39	**Manufacturing**	
40	Design first generation sensors	Management[50%],Administrative,App Technical[200%]
41	Select manufacturer and start volume tests	Management,App Technical[200%],Administrative
42	Manufacture First Generation Sensors (50 copies)	App Technical
43	**Sales and Marketing**	
44	Create sales and marketing Plan	Sales Professional[200%]
45	Submit Patents	echnical[25%],Sales Professional
46	FDA Approval	Management[25%],App Technical[25%],Sales Professional,Administrative
47	Create plan for publicity / demand creation	Management[25%],Administrative,App Technical,Sales
48	Organize test subjects	Management,Administrative[500%],Sales Professional
49	Introduce concept to selected MD's	istrative[25%],Sales Professional[200%]
50	Create Instructional Video	Sales Professional[200%]
51	Investigate Cardiologist Review of Test Data	al,Management[25%]
52	Alliances / product sharing	Sales Professional,Management[25%]



2 **Start Up - Hiring, space, general Organization**
Work quickly to build work force into a competent force for Internet Deployment

4 **Accounting System**
- utilize Profit
- Get chart of accounts
- set up prelimanary A/P
- Banking relations
- Payroll service

5 **Benefits Plan**
- set up health Insurance
- Stock Options (lawyers)

6 **Start recruiting**
- Set plan for recruiting technical talent
  - identify key technical resources that are required
  - identify recruiting agencies to help locate candidates
  - Set salary guidelines
  - Start interviewing

7 **Deploy Pr totype System (25 Patients) (Start+ 3 Months)**
Complete an end to end test
- demonstrate download, test operation, upload
- utilize the best sensors that can be produced in 2 months
- Run tests on at least 20 patients
- Produce plan for getting to production quality by start + 6 months

8 **Internet Deployment**
Fast start will employ ATI facilities to perform these tasks.
ATI possesses the infrastructure to begin work immediately

0 **Acquire appropriate hardware and software**
Utilize the ATI Infrastructure to establish an operating environment
- Oracle / Application Server
- Cardiobeat.com web page
- Messaging Capability

Configure a first generation server for performing the test
- Set up with Oracle and utilize for Testing and Production
- This machine should be capable of handling at least 100,000 tests per month.
- Would include DASD to hold 5 million tests.

1 **Implement First Generation Web Servers**
For the new box -
- Install Unix
- Install Oracle with OAS
- Install all other development tools

2 **Create cardiobeat.com Web Page**
Design and code Cardiobeat.com home web page
- Company Introduction
- Application for test patient
- Job opportunities

3 **Evaluate and select ISP's**
Find backup computing resorces for supporting high volumes that cannot be handled internally.

14 **Plan for general deployment volumes**
Planning for volumen production and testing to the extent possible.

16 **Create Heart Test dB**
This database holds the test data for each client
Archiving will be considered in the second phase
Design objective for first base should be 1,000,000 tests
Collaborate with the application code team for the database design

17 **Build Heart Test Download**
Key Task -
- Define tools for storing and delivering Application Code to Desk Top
- Version Control
- Tracking "open" customers
- Web Pages to guide customer through download
- "On Client" Application version detection and management
- Customer profile update
- Design the Client side Q&A

18 **Build Client Data Retrieval**
Code and Client interface to retrieve and deliver archived tests and trend line calculations.

19 **Code Test Data Comm tools for user and back room**
Tools for routing tests and other patient information to doctors and hospitals
- Client side design to collect name and routing information
- Form to order routing
- Confirmation of routing
- Emergency Procedures for out-of-line conditions

20 **Build doctor's office / clinic test procedure**
Create logic to take tests, deliver to the doctor for immediate evaluation
Characterize differently form individual Customer tests in amount and sophisitcation of the data.

21 **Trendline evaluation and Reporting**
Multiple tests can be scrutinized for trends in cardiovascular performance
- define trend analysis requirements
- build test code
- define initial graphical presentations

22 **Create Instructional Video Management Facility**
Video to instruct and demonstrate proper sensor attachment and other procedures to the customer.

23 **Perform Heart tests employing Downloaded App Code**
Organize Patients (25)
Get test equipment installed on several test PC's
download code over the web
run the tests
Observe / change procedure

25 **Create Administration dB**
Start work on the Admin DB with resources that can be freed from the main effort.

26 **Build (Admin) Patient set-up**
Procedures for enrolling and tracking each customer
Do the design work necessary to develop the data base and code logic to prepare for a push on these apps in the next phase.

27 **Customer Database Maintenance**
Transactions to
- create accounts
- maintain tests purchased inventory
- communicate account status to the customer
- monitor account status internally

49 **Introduce concept to selected MD's**
Part market research and part sales to the doctors -
assess receptivity
educate
develop sales strategy based upon experience

50 **Create Instructional Video**
collaborate with the distribution group on the instructional video

51 **Investigate Cardiologist Review of Test Data**
Compile a coherent testimonial from individuals of stature in the Medical Profession.

52 **Alliances / product sharing**
Identify support facilities like video players
- determine the requirements
- identify suppliers
- negotiate and close

EXHIBIT 3

GMcBrid /cardiob at.com

Fr m: SoftQue [royce@softque.com]
Sent: Monday, August 23, 1999 10:03
To: George McBride
Subject: FW:

George I thought you might want to see this. rlr -----Original Message-----
From: Warren Williamson [mailto:warren@wlwill.com]
Sent: Tuesday, August 17, 1999 1:45 PM
To: royce@Softque.com
Subject:

Bob:
Following are my thoughts and observations about the next generation Thorasic Impedance Measurem nt System: The present Thorasic Impedance Measurement System design can be reduced greatly in size, cost, and power consumption by incorporating newer microprocessor technology which is now available. In particular, Digital Signal Processing (DSP) techniques can be used to perform the filtering and other signal processing functions which are implemented in the current design as individual amplifier and filter circuits. There are numerous DSP processors available now which are capable of performing these functions. In addition, performance will be improved with the use of these techniques. Much of the size and cost of the present design relates to the connectors, switches, display, and other interface components. There is plenty of opportunity for reduction in these areas. Another step which can be taken if necessary to futher reduce size is to use Surface Mount Technology. Even if not necessary for size reduction, it may be the best choice as this is a more modern assembly method and is becoming very widespread. The first step in the redesign proc ss is to review the available microprocessor and DSP technology and select the appropriate processor based on cost, power consumption, external components required, and other design consideratons. We also need to carefully specify the product functionality with the features necessary for the way we intend to apply it. Then we can do the circuit and firmware design and produce circuit boards and prototypes. I'm looking forward to working with you again on this project. Warren

EXHIBIT 4

Answers to questions regarding Impedance Cardiography

Acceptance:

Impedance has not been widely accepted because its biophysics is not well investigated and the factors involved in the production of the signal are multiple and poorly understood. Impedance began to be promising about the same time that cardiac ultrasound came onto the scene. The physics of sonar was well researched; the technology proliferated rapidly and was marketed by many startup companies in the private sector. Virtually all of the research on impedance cardiography was done for the Apollo space flight by a team of researchers under Dr. William Kubicek, a physiologist at the University of Minnesota. The University held the patents on the device as the Minnesota Impedance Cardiograph. Like most universities, it was a disinterested entrepreneur, absent motivation from extensive clinical testing the technology languished. Computer power had to increase sufficiently to detect and assemble the average by separating the wandering "dirty" signal from cardiac impedance. Until the computing power was available, impedance would be seriously handicapped when comparing values against the "gold standard" for measuring cardiac output - measure the average of multiple cardiac cycles collected over a period of multiple seconds to minutes. Because it's accuracy was in question, and all of the gold standards for measuring cardiac output were invasive and thus not applicable to day to day monitoring any place but the intensive care unit, there was no precedent for it's use in the outpatient clinic setting .The medical community is conservative in embracing new ideas especially those not completely understood and explained by "hard " science facts and principles. Of course the electrocardiogram is still not completely explained and understood by hard science biophysics, but its utility has been accepted and validated through extensive clinical correlation and research, and even now new insights are gained annually about the electrocardiogram.

Except for a few of us, there is little clinical experience with this technology and therefore the opportunity for, and participation in, experience with the technology must occur before widespread acceptance can follow.

This is where a research partnership with a few large hospitals could be helpful. To validate the technology requires correlation with invasive measurements and one large group that almost always gets monitored early post operatively are coronary bypass patients and heart surgery patients in general. Invasive monitoring lines are removed as early as possible to reduce the risk of infection, but if a noninvasive technique can be shown to be reasonably accurate, safe and cheaper than the invasive one, every hospital administrator in the country providing cardiac surgery and cardiac care services will want to pursue the more cost effective strategy. Considering the substantial costs of invasive monitoring and the affordable cost of impedance, the technique could be extended to cardiac rehabilitation and out patient heart failure monitoring and management. Congestive heart failure (CHF) is the most costly DRG for Medicare and is projected to expand almost exponentially in our aging population over the next 3 decades. The opportunity to substantially reduce the number of costly hospitalizations in the ever growing heart failure population and its economic impact on business government and society cannot be under estimated. I firmly believe that CHF is so much better treated with outpatient impedance directed therapy than with the typical inpatient course of care that only under extreme conditions such as sepsis or malignant arrhythmias should a patient with CHF be admitted to hospital. CHF is not a disease requiring hospitalization for it's optimum management. The disease must be managed in

the day to day environment where the patient lives. The strict diet, activity, and fluid restriction of the hospital environment only works until the patient leaves to go home, but is not applicable once he gets home, so he gets into trouble a little later and back he comes for another round of expensive care in the "ivory tower". Accurate, scheduled, hemo-dynamic surveillance can detect impending deterioration and direct appropriate treatment before the patient's condition reaches crisis proportions.

2) Demand and pricing:
The formula you used is right. If its' accuracy is valid then it's utility should be able to be proven. If it is perceived to have utility, widespread usage is inversely proportional to price.

What we are considering is a new paradigm for "medical technology business" where the profit has traditionally been made from selling the machine or "hardware". The new model is service or software analogous in that the machinery is viewed as a linkage device decreasing in purchase price all the time while ISP's underwrite the hardware purchase to get consumers tied to long-term service agreements. Digital satellite dishes, cell phones, digital pagers, and essentially all new age machinery are useless without service providers. Hell, even your car has OBD so you can't tune it without special software in the hands of a select few service providers.

Jim Buell 9-18-99

EXHIBIT 5

DEMO - Message (Rich Text)

File Edit View Insert Format Tools Actions Help

Reply Reply to All Forward

Arial 10 B I U

This message contains formatting that is best viewed with Microsoft Word. Click here to display in Word.
You forwarded this message on 10/18/1999 08:09. Click here to find all related messages.

From: SoftQue Inc. [royce@softque.com]
To: George McBride; Larry K. Macdonald
Cc:
Subject: DEMO

Sent: Sat 10/16/1999 17:47

CBI

CardioBeat.com
Engineering Department
3427 East Harbor - Mesa, AZ. 85213
www.cardiobeat.com
Email - royce@cardiobeat.com
Ce. 602/334-5[illegible]
Fax. 480/833-6[illegible]

10/16/99 5:20:38 PM

Status of 2nd generation Portable Cardiac Lab (PCL)

George I guess that you have been using this PCL software as a basis and renaming it as "Cardiac Track" software.

Choices:

1. Assuming that we do NOT produce an interim product for a DEMO:

3rd generation CardiacTrack software:
I on the other hand have always believed that if we ever got funding we would start over with Client and Server software designed around the basic research and math that both Dr. Buell and I have worked in the original DOS based version know as the Cardiac Performance Lab (CPL). This would insure the most efficient use of the very small amount of time allocated to develop this product. This is a major change and it will require a complete rewrite to produce an efficient product that is small in size and easy to download over the net.

People Required:
With a couple of quality programmers and at least one and possible two high quality engineers to work me in my division of the company, then I believe that we can produce this product in a timely manner.

I would have the job of **coordinating** four major efforts:

1. A patient hardware/interface device with four lead electrode assembly
2. Client software. (User)
3. Server software (Database & intelligent reports)

(HTML) - Message (Rich Text)

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From: SoftQue Inc. [royce@softque.com]
To: George McBride; Larry K. Macdonald
Cc:
Subject: DEMO

Sent: Sat 10/15/1999 17:47

4 Working with the WEB developers on specifications Making sure everyone is on the same page using the same specifications These specifications will be somewhat liquid and will change as required The engineers/programmers will want some things and the Visual Basic programmers on both the Client and Server products will want their ideas incorporating as well as the WEB designers/programmers

The server product would be the most complex product and would require a great deal of coordination between the Visual Basic programmers and the WEB programmers

With my knowledge of the overall product and the creative input of the programmers and engineers we should end up with a very high quality product.

2. Assuming that we DO produce an interim product for a DEMO:

2nd generation Portable Cardiac Lab (PCL)
I would continue to develop the PCL software and make it work and act somewhat like the CradiacTrack product.

If I do NOT sell my company in a timely manner I will need a least one programmer to work with me on a full time basis I would want this individual to be a full time employee We would need funding of some kind if this is the case.

The attached flowchart assumes that we use the interim product All most all of this work would have to be repeated when we start deigning the CardiacTrack product. Of course some of it could be used but not much

I am NOT in favor of this manner of time management. I realize it may help to sell the product and it may have to be done.

Developing the PCL software could also backfire on us, as the device a will not look or feel like the actual product. If you show a physician a "Stand Alone System" and then tell him your going to add it up he may not understand the concept. Or he may not want to.

I believe that producing a PCL demo will cause MAJOR problems but if you *all insist* that it be done then lets get a bit of funding and do it.

I need feedback on this – is this what you need for Tuesday?

overview.jpg (64 KB)

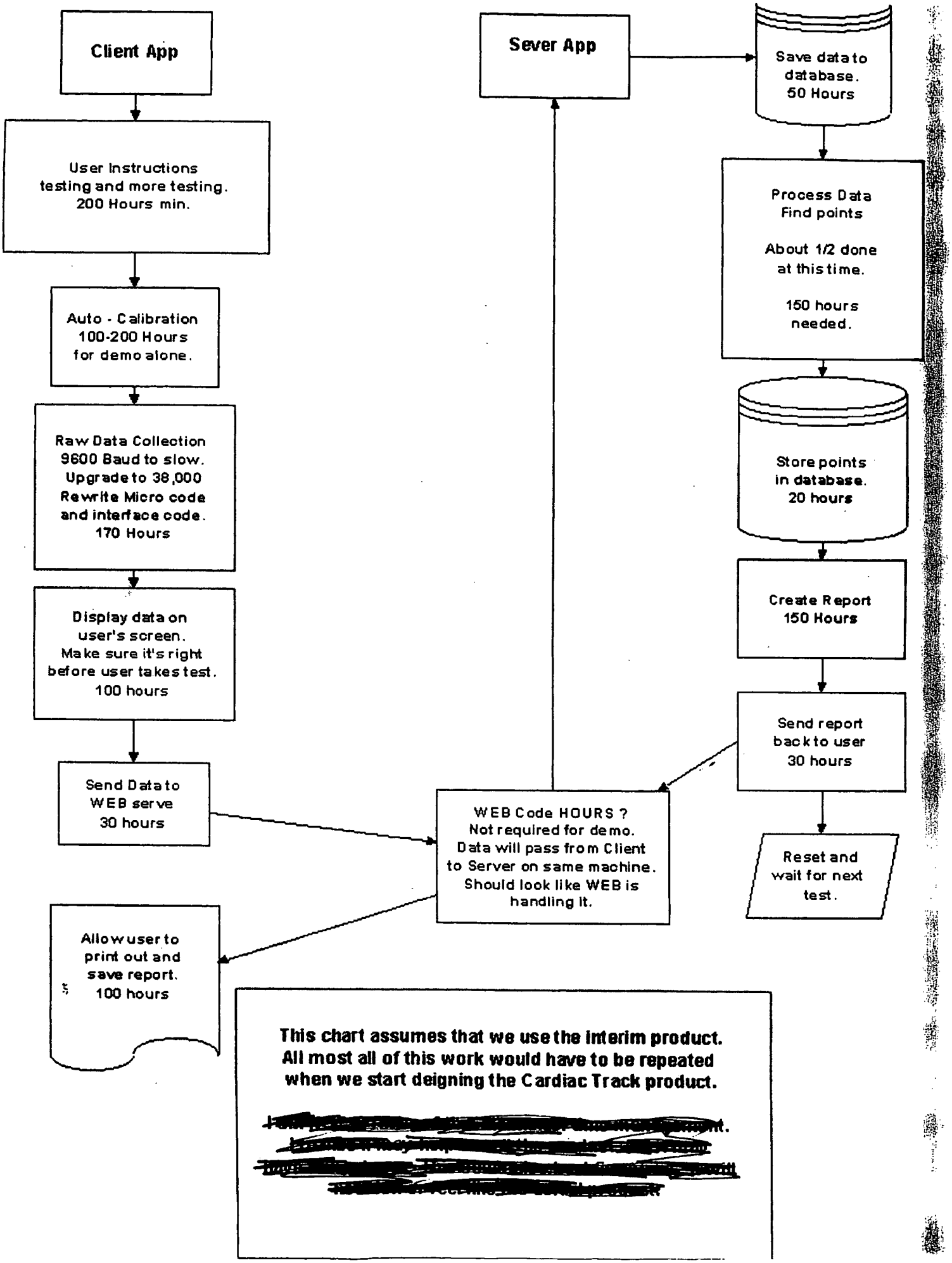
Client App
User Instructions
testing and more testing.
200 Hours min.
Auto - Calibration
100-200 Hours
for demo alone.
Raw Data Collection
9600 Baud to slow.
Upgrade to 38,000
Rewrite Micro code
and interface code.
170 Hours
Display data on
user's screen.
Make sure it's right
before user takes test.
100 hours
Send Data to
WEB serve
30 hours
Allow user to
print out and
save report.
100 hours
Sever App
Save data to
database.
50 Hours
Process Data
Find points
About 1/2 done
at this time.
150 hours
needed.
Store points
in database.
20 hours
Create Report
150 Hours
Send report
back to user
30 hours
Reset and
wait for next
test.
WEB Code HOURS ?
Not required for demo.
Data will pass from Client
to Server on same machine.
Should look like WEB is
handling it.
This chart assumes that we use the interim product.
All most all of this work would have to be repeated
when we start deigning the Cardiac Track product.

EXHIBIT 6

Cardiobeat.com
a paradigm shift in cardiovascular health

George McBride
gmcbride@cardiobeat.com
(480) 419-3957
17350 North Hartford Drive
Scottsdale, AZ 86255

December 22, 1999

Overview of software development status for the CARDIO-TRACK phase one product deliverable

Server CARDIO-TRACK data reduction and analysis module code

WEB data transfer application

Client application

- User friendly tools
  - Help
  - AVI Videos (Sent with startup CD)
  - Checks for misplaced sensors
  - Checks for correct waveforms
  - Click once to start test
  - Press space bar or mouse to halt or suspend test
- Automatic Transmission from the host server to client
  - Update Client application software (real time)
  - Data movement
- Transmission to the host server from the client
  - Data movement
- Server processing
  - Processes data
  - Create reports
  - Routing to client & physicians
    - E-Mail Reports
    - Emergency calls
- Database
  - Storage of Client data
- Communications between parties (patient and physician)
- Customer service module

Patrick Smith – Data Base Administration

- The Oracle decision - what are the alternatives and why Oracle
- Scalability
- Web Interface capabilities
- Hardware Options

Brett Scott – Microsoft Visual Basic / Web Coding

- The Microsoft environment
- Moving protected Data
- The User Interface

Bob Gubser – Sensor Manufacturing

- Describe PRA
- Review Cardiobeat memo on sensor engineering and manufacturing
- Discuss early steps to produce prototype

a paradigm shift in cardiovascular health

George McBride
gmcbride@cardiobeat.com
(480) 419-3957
17350 North Hartford Drive
Scottsdale, AZ 86255

Cardiobeat.com Software Status Review 22 December 1999

Bob Royce

- Overview of software environment
  - CARDIO-TRACK test
  - User friendly tools
    - Help
    - Videos
    - Checks for misplaced sensors
  - Transmission from the host server to client
    - Application software
    - Data movement
  - Transmission to the host server from the client
    - Data movement
    - Routing to physicians
  - Server processing
  - Database
  - Communications between parties (patient and physician)
  - Customer service module
- CARDIO-TRACK test code
  - Calculations
  - Reporting
  - Data transfers

Patrick Smith – Data Base Administration

- The Oracle decision - what are the alternatives and why Oracle
- Scalability
- Web Interface capabilities
- Hardware Options

Brett Scott – Microsoft / Web Coding

- The Microsoft environment
- Moving protected Data
- The User Interface

Bob Gubser – Sensor Manufacturing

- Describe PRA
- Review Cardiobeat memo on sensor engineering and manufacturing
- Discuss early steps to produce prototype
- Characterize the prototype

Items for the future

- Help Support
- "Use" Video's
- Customer Support Modules
- Volume test storage subsystem

George McBride
gmcbride@cardiobeat.com
(480) 419-3957
17350 North Hartford Drive
Scottsdale, AZ 86255

Characterize the prototype

Items for the future

Help Support
"Use" Video's
Customer Support Modules
Volume test storage subsystem

EXHIBIT 7

W. L. Williamson & Associates
Consulting Engineers
528 S. Extension Rd.
Mesa, Az. 85210
PH (480) 833-5202 FAX (480) 833-5529
www.wlwill.com

Robert L. Royce
Vice President
Cardiobeat.com

January 7, 2000

Re: Quotation # 000107-1

Bob:

Considering the very short time frame and limited resources available, I believe the following is the best approach for this step in the Impedance Measurement development:

1. Reduce the size and cost by eliminating functions not needed in the present concept. Keep the basic approach the same -- analog signal processing followed by the A/D and serial transmission to the PC.

2. Redesign the necessary portions to eliminate those problems which you have identified in the present prototypes.

3. Make other cost and size reduction changes where they can be identified as "low risk", i.e. those that we can be reasonably sure will not add a lot of delay to the program.

We should be able to produce something approximating the size of the enclosure which I showed you during our meeting Thursday. Although I can't cost everything out until the design is done, we should be able to build it in 100 pc. quantities for something in the neighborhood of $50 -- $75 each.

Early in the redesign phase we should also look at some other potential cost savings. For example, the filters we are currently using account for $13 of material costs (100 pc. quantities). How much filtering do we really need? The requirement should be less if we have no connection to the power line system. Also, we can use a microcontroller with a built in A/D converter thereby cutting the cost of the two separate devices approximately in half. There are other potential savings that would not add much development time. If we can quickly evaluate the potential savings vs. risk, we should do so.

Following is my proposed development plan. There will necessarily be some overlap in the steps as proposed. This is a very aggressive development schedule. However, it is achievable. I am assuming I will not be responsible for any PC software development.

Because of the developmental nature of the project, I have quoted "not to exceed" costs. The actual costs may be somewhat less, but not more than the amounts below unless the scope of the development changes by mutual agreement. Engineering time is billed at $110/hr. Technician/PCB Layout time is billed at $60/hr. Materials and other expenses are billed at cost + 20%.

Phase 1.

Redesign of known problem areas. Evaluation of potential cost/size saving circuit redesign. Prototyping and test of new circuits.

Time -- 2 weeks Maximum Cost -- $ 11,500

Phase 2.

Finalize circuit design and schematic. Firmware redesign. Mechanical design.

Time -- 1 to 2 weeks Maximum Cost -- $ 9,500

Phase 3.

PCB design and layout. Fabricate prototype PCB. Purchase components. Build and Test Prototype.

Time -- 2 weeks Maximum Cost -- $ 5,600

Total Time -- 5 to 6 weeks Maximum Cost -- $ 26,600

Terms - $ 8,500 with order
$ 8,500 at completion of Phase 1
$ 8,500 at completion of Phase 2
Balance of Costs at Completion of Phase 3.

By

Warren L. Williamson

EXHIBIT 8

Timing of Test Waveforms
WLW – 2/1/00

The Test waveforms consist of ramping waveforms (sawtooths) on all four channels. All four channels are continuously transmitted at 38.4 Kbaud in the format as described in "Cardiobeat Communications Protocol (Preliminary). Since 10 bits are transmitted for each byte (8 data bits + START + STOP), the maximum number of bytes per second which may be transmitted at this rate is 3840. We actually transmit 3200 bytes per second. Two bytes are transmitted for each channel and there are 4 channels so the sample rate is 400 samples/second/channel. (4 Channels x 2 bytes/channel x 400 samples/second = 3200 bytes/second)

The Channel 0 data is incremented once for every transmission (400 times per second). Therefore it makes a complete cycle of 256 steps in 256/400 seconds, or .64 seconds.

The Channel 1 data is incremented every other transmission (200 times per second). There are two transmissions of the same data. Therefore it makes a complete cycle of 256 steps in 256/200 or 1.28 seconds.

The Channel 2 data is incremented every fourth transmission (100 times per second). There are four transmissions of the same data. Therefore it makes a complete cycle of 256 steps in 256/100 or 2.56 seconds.

The Channel 3 data is incremented every eighth transmission (50 times per second). There are eight transmissions of the same data. Therefore it makes a complete cycle of 256 steps in 256/50 or 5.12 seconds.

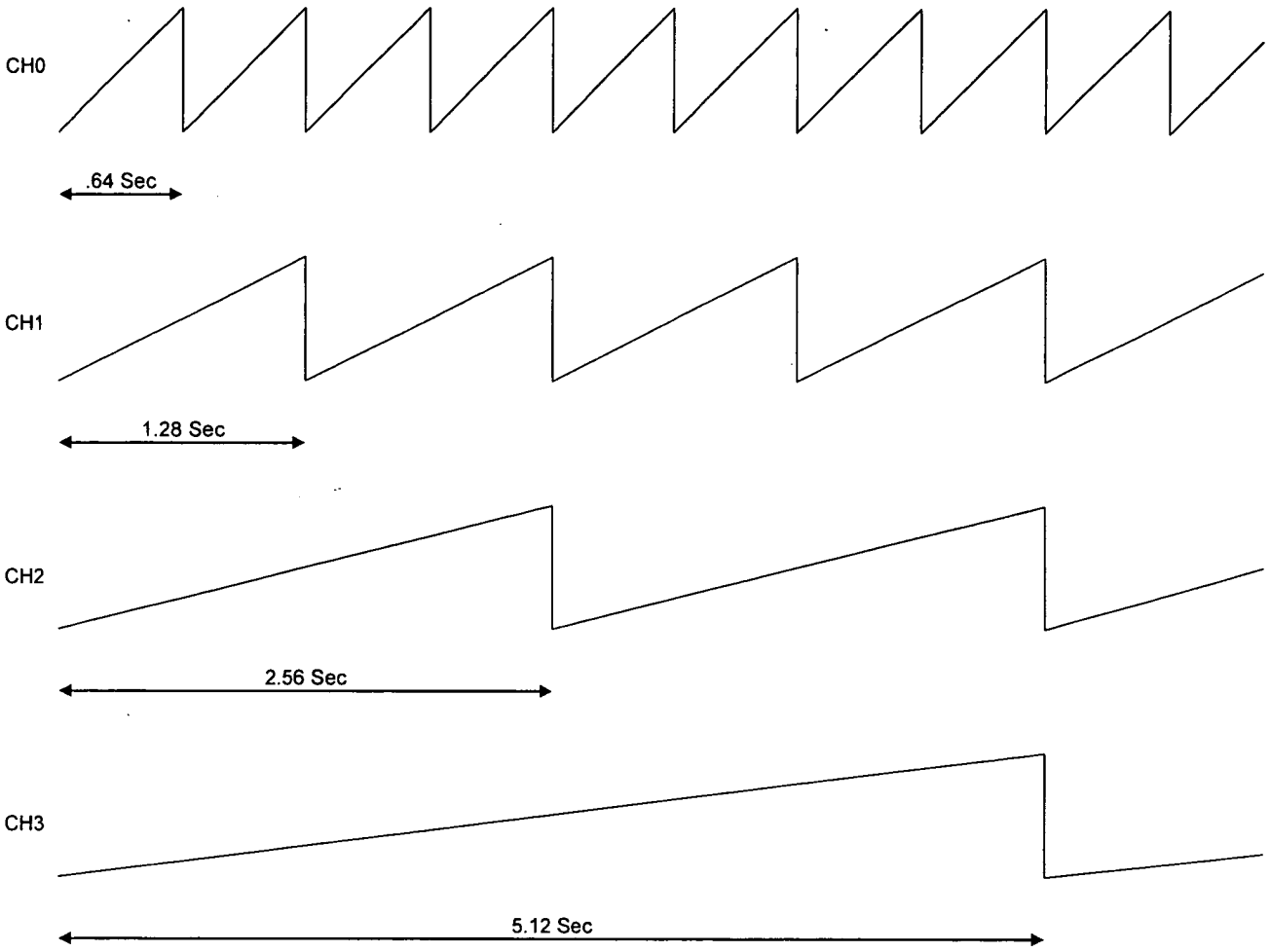
CH0
.64 Sec
CH1
1.28 Sec
CH2
2.56 Sec
CH3
5.12 Sec

EXHIBIT 9

CARDIOBEAT COMMUNICATIONS PROTOCOL

PRELIMINARY

WLW – 2/9/00

REV1 – 2/21/00

Communication between the Impedance Measurement Unit and the Host is via a full duplex RS232 connection at 38.4 Kilobaud. Measurement data are sent to the Host as byte pairs, MSB followed by LSB. The MSN (Most Significant Nibble) of the 8 bit A/D data is sent as the lower four bits of the MSB. The LSN of the 8 bit A/D data is sent as the lower four bits of the LSB. Each byte pair conveys the following information:

1. The Byte ID (LSB or MSB) (b4 = 0 for LSB, b4=1 for MSB).
2. The A/D channel number (0 - 3) of the data contained in this pair (b7 and b6 of the MSB)
3. The A/D data MSN or LSN (b3 – b0).
4. Calibrate/Normal mode. (LSB b6 = 1 in calibrate mode)
5. Note that b5 is always 1 in both MSB and LSB. This insures that no data byte will be an ASCII control character.

MSB Contents	b7 CH MSb	b6 CH LSb	b5 1	b4 1	b3,b2,b1,b0 A/D MSN
LSB Contents	b7 spare	b6 MODE	b5 1	b4 0	b3,b2,b1,b0 A/D LSN

The channel identification is as follows:

CH0 – ECG

CH1 – dz/dt

CH2 - DZ

CH3 – Z0

Each channel is sampled and its data transmitted in turn so that 8 sequential bytes represent one sample of each of the 4 channels.

Using this protocol, up to 480 data points per second per channel may be transmitted at 38.4 Kbaud. (10 bits x 2 bytes x 4 channels x 480/sec). The actual data rate will be approximately 400 data points per second per channel.

EXHIBIT 10

CARDIOBEAT DATA CONTENTS
WLW – 2/28/2000

Each data sample may be represented as an 8 bit binary number with a value of 0 to 255 decimal. For the Z0 data (Channel 3) the data is unipolar with a scale of 50/255 Ohms per step. The value in Ohms may be obtained by multiplying the 8 bit unsigned value by .196.

The remaining 3 channels are referenced to approximately ½ scale (128 decimal). The actual reference value is the value obtained when the impedance device is in the CALIBRATE/NULL mode, hereinafter denoted NullValue. In operation, the real world value of the signal may be computed by subtracting NullValue from the signal value and multiplying by the appropriate scale factor. (Subtracting NullValue from the binary number puts the number in a 2s complement, 7 bit plus sign format)

The Scale factors are as follows:

CH0 – ECG: 27.8 microVolts/step. (3.56 mV full scale)
CH1 – dz/dt: -.0156 Ohm/sec./step (-2 Ohm/sec full scale)
CH2 – DZ: .00156 Ohm/step (.2 Ohms full scale)
CH3 – Z0: .196 Ohm/Step (50 Ohms full scale)

Examples:

Assume the CALIBRATE/NULL mode produces a NullValue of 130 on CH0, CH1, and CH2. (In reality the three readings may be slightly different.)

Z0: 25 Ohms will produce a binary number of ~ 128.
128 x .196 = 25.088 (Ohms)
(Var x .196) = ZO

DZ: -.1 Ohms will produce a binary number of ~ 66.
(66 - 130) x .00156 = -.09984 (Ohms)
(Var – Null) x .00156 = DeltaZ

dz/dt: -1 Ohm/sec will produce a binary number of 194.
(194 – 130) x -.0156 = -.9984 (Ohms/sec)
X **(Var – Null) x .0156 = dzdt**
(Var – Null) x -.0156 = dzdt **(Note negative sign on factor)**

ECG: +1 mV peak will produce a binary number of 166.
(166 – 130) x .0278 = 1.0008 (mV)
(Var – Null) x .0278 = ECG

The way I read this I would compute as shown in blue.
Right or Wrong.
rlroyce@yahoo.com

CH0 – ECG

3.56 mV full scale. The ECG data is centered around half scale. That is, the output of the ECG amplifier is biased to 2.5 Volts with no signal present before being input to the A/D converter. With no signal, the binary data transmitted will be approximately 128 decimal (80 Hex). A positive signal on Lead 2 with respect to Lead 3 produces positive data.

CH1 – dz/dt

-2 Ohms/Sec Full Scale. The dz/dt data is centered around half scale. That is, the output of the dz/dt amplifier is biased to 2.5 Volts with no signal present before being input to the A/D converter. With no signal, the binary data transmitted will be approximately 128 decimal (80 Hex). The sense of the signal is inverted – a decreasing impedance produces a positive going signal.

CH2 – DZ

.2 Ohms full scale. The DZ data is centered around half scale. That is, the output of the DZ amplifier is biased to 2.5 Volts with no signal present before being input to the A/D converter. With no signal, the binary data transmitted will be approximately 128 decimal (80 Hex). An impedance greater than Z0 produces positive data (> 128). An impedance less than Z0 produces negative data (<128).

CH3 – Z0

50 Ohms full scale. The Z0 data is zero based. Zero Ohms produces a data value of zero. 25 ohms produces a data value of 128 (80 Hex). 50 Ohms produces a data value of 255. (FF Hex).

EXHIBIT 11

W. L. WILLIAMSON & ASSOCIATES, LTD
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528 S. Extension Rd.
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PH (480) 833-5202 FAX (480) 833-5529
www.wlwill.com

Robert L. Royce
Cardiobeat.com

March 6, 2000

Bob:

I am attaching our invoice # 4772 in the amount of $8500. Per our agreement, the payment is due upon completion of Phase 2. Although the phases have become overlapped, we are certainly well along with Phase 3.

Following is an accounting of the actual expenditures to date:

Engineering - $14,860.00

Technician - $ 5,185.00

Components - $ 1,895.94

Total - $ 21,940.94

The prototype is working well as far as I have been able to test. However, I have not yet checked with live signals. It will be very helpful to have the ability to display the real data. Do you have anything to give me yet?

We have most of the components to build several more prototype units. I estimate the labor to build and test them at $500 each. This is outside the scope of our agreement and will represent additional charges. It may make sense to do a PCB re-layout before building more units. I will give you my recommendation on that after the prototype has been completely checked out.

I am very happy with the way the prototype is shaping up. It is much closer to the desired end product than originally envisioned by my proposal. I can now begin to put together some cost figures for 100's and 1000's of units.

Warren